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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,373	07/18/2003	Jennifer L. Whistler	316E-001510US	4987

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EXAMINER	
ULM, JOHN D	
ART UNIT	PAPER NUMBER
1649	
MAIL DATE	DELIVERY MODE
10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,373	WHISTLER ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *12 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 13-25 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 to 29 are pending in the instant application. Claims 19 and 21 have been amended and claims 30 to 78 have been canceled and as requested by Applicant in the correspondence filed 07 May of 2007.

Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 12 and 26 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 25 July of 2006.

Claim Rejections - 35 USC § 112

Claims 1 to 11, 13 to 25 and 27 to 29 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. These claims encompass subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention essentially for those reasons of record in the office action mailed 06 November of 2006.

In so far as claims 1 to 11 and 13 to 17 require an inhibitor that reduces specific binding of the G protein-coupled receptor to a GAST1 polypeptide, the instant specification fails to describe the genus of compounds that could potentially be

encompassed by this limitation. Because the instant specification fails to define this genus of compounds, an adequate search of the claimed method is impossible. If one assumes that compounds other that the c terminal peptide of GAST 1 exist that possess the required inhibitory activity, then the instant claims would encompass any method that requires the administration of any of those compounds to an organism. The discovery of an inherent property of a prior art process can not serve as a basis for patenting that process. See *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A U.S. patent to Dart disclosed inoculation using *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating.). However, any such method can not be identified because the instant specification does not describe the genus of compounds that reduce specific binding of a G protein-coupled receptor to a GAST1 polypeptide "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention" (Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966).

Further, the recitation of a functional limitation in the absence of the structural element or elements required to provide the recited function constitutes nothing more

than a wish to know the identity of any compound having the required function. A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt , 708 F.2d 712,>714 - 715,< 218 USPQ 195>, 197< (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See M.P.E.P. 2164.08(a)

These issues are equally applicable to claims 18 to 25 and 27 to 29 in so far as they require "a polypeptide that increases agonist-induced down-regulation of the G protein-coupled receptor". One of ordinary skill in the art of molecular biology has no reasonable expectation that the majority of polypeptides having as little as 70% sequence identity to as few as 15 amino acids of SEQ ID NO:2 are going to have the required activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single

> embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Because the instant specification does not identify those amino acid residues in SEQ ID NO:2 which are critical to the structural and functional integrity of a protein comprising that sequence, identify a structurally analogous protein for which this information is known and could be applied to the instant protein by extrapolation, or even provide a single working example of an intentionally modified protein of the instant invention, an artisan can not change even a single residue within the amino acid sequence of SEQ ID NO:2 and predict the effects of that change on the performance of that protein "by resort to known scientific law".

Applicant has essentially traversed this aspect of the rejection on the premise that the instant application provides a working example of the claimed method. Actually, it does not. The instant claims are examined in so far as they are drawn to the elected invention. Claim 1 is examined in so far as it is drawn to a method of inhibiting agonist-induced down regulation of a delta opioid receptor ***in vivo*** by the administration of an inhibitor that reduces specific binding of that receptor to a GAST1 polypeptide. The instant specification discloses not a single working example of an *in vivo* method of treatment nor does it identify an analogous method that was known in the prior art and from which guidance could be obtained. In fact, it fails to disclose even a single *in vitro* working example of the claimed method, in which agonist-induced down regulation of a delta opioid receptor has been inhibited by the exogenous administration of any

compound to an intact cell. This is also true for the method of claim 18, which is being examined only in so far as it encompasses a method of enhancing agonist-induced down-regulation of a delta opioid receptor ***in vivo*** by the administration of a polypeptide that increases agonist-induced down-regulation of that receptor. There is absolutely no evidence of record that the exogenous administration of a polypeptide comprising any or all of SEQ ID NO:2 will have any effect whatever on the agonist-induced down-regulation of a delta opioid receptor in an intact cell.

Not only does the instant specification fail to provide working examples of the claimed methods, it also fails to provide any reasonable expectation that such methods could be developed. The site of interaction between a GAST protein of the instant invention and a delta opioid receptor is intracellular. The only compounds that are described in the instant specification that have the activities required by the instant claims are polypeptides. One of ordinary skill in the art of molecular biology has no reasonable expectation that an exogenously administered polypeptide of the instant invention will have any effect whatever on the intracellular interaction of a delta opioid receptor with any GAST protein contained within that cell, as would be required for the functionality of the claimed method. The instant specification nether discloses how to obtain the cellular internalization of a polypeptide of the instant invention nor identifies any prior art reference in which an analogous method has been practiced with a different peptide. Applicant urges the "intrabodies" are known in the art but fails to identify a single peer reviewed publication describing the *in vivo* administration of an "intrabody" for clinical effect. A patent is granted for a completed invention, not the

general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

> "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not following the guidance presented therein and practice the claimed method without first making a substantial inventive contribution.

In so far as the instant claims encompass a method of treatment by administering a polynucleotide, one of ordinary skill would not reasonably expect the exogenous administration of a nucleic acid encoding all or part of a polypeptide of the instant invention to a mammal to have a clinical effect because the art of gene therapy has not developed to the level of a routine practice in the clinical arts. It is noted that several genetic defects associated with diseases such as sickle cell anemia and cystic fibrosis are well known in the art, as are the genetic corrections needed to cure these diseases, and yet the art of record does not show that these diseases have been successfully treated by gene therapy. It is further noted that a number of proteins that are critical to the proliferative and invasive nature of cancer cells, such a telomerases

and angiogenesis stimulators, have been well characterized in the art of molecular biology before the making of the instant invention and yet the art of record does not describe a single instance in which a cancer has been successfully treated by genetic therapy. As stated above, the claimed method is not enabled because one of ordinary skill in the art of molecular biology can not follow the guidance provided by the instant specification, combined with a routine knowledge of the art, and practice in claimed method with any reasonable expectation of success.

Response to Arguments

Applicant's arguments filed 07 May of 2007 have been fully considered but they are not persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JOHN ULM
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